

REMARKS

The application is believed to be in condition for allowance.

Claims 1-14 have been amended and remain in this application. Claims 15-16 are new and is based on amended claim 1.

Claims 1, 2, 4, and 10 were objected to for the use of the term "means". The claims have been amended to avoid this term.

Claims 1, 2 and 5 were rejected under Section 102, as anticipated by HABER et al. 5,378,233.

Claims 3, 11, and 7 were rejected under Section 103, as obvious over HABER in view of KNAUER 5,514,097; claims 4 and 12 over HABER in view of BALKWILL EP 0554995; claims 6 and 9 over HABER in view of WALTERS et al. 6,096,010; claim 10 over HABER in view of KNAUER; claim 8 over HABER in view of WALTERS '010 and further in view of WALTERS et al. 6,221,053; claim 13 over HABER in view of WALTERS '053; and claim 14 over HABER in view of WALTERS '010.

Both amended claim 1 and new claims 15-16 are believed novel and non-obvious over the prior art.

The actuating means is recited as an actuator configured to inject a dose of the medicament upon actuator activation, and comprises i) a plunger rod connected to the container, ii) an actuating spring arranged to said plunger rod

and configured to push said plunger rod into said container for expelling the medicament through a connected needle.

The claims further recite that an activator configured to release the plunger rod from a position where the actuating spring is tensioned.

Additionally, the claims recite a needle shield arranged to the body and slidable between an extended and a retracted position in relation to the body, wherein, the needle shield is configured so that upon penetration of the needle into a patient, when moved or pushed towards the retracted position, the needle shield acts on the activator, which activator in turn releases the plunger rod for injecting the dose.

In claim 16, the recitation includes that the needle shield is arranged ... so that injection of the dose is initiated by the needle shield releasing the plunger rod when moved a certain distance.

This combination of features is not taught or suggested by the prior art.

In contrast to the present invention, the device according to HABER comprises two cylinders with stems or plunger rods and drive springs. These are tensioned by dose setting nuts creating pressure on the medicament inside the cylinders. When a dose is to be delivered, the front end of the injector, having a needle shield, is moved so that the needle is exposed and pushed into the injection site. Further movement of the needle shield

causes it to come in contact with the needle cannula assembly, where the proximal end of the needle then penetrates a septum and displaces a ball of a check valve. This allows the pressurized medicament to be expelled from the cylinder through the needle and into the tissue of the injection site.

Thus, one distinct difference between the claimed invention and the device of HABER is that the injection is initiated by the needle shield releasing the plunger rod when moved a certain distance. In HABER, there is no connection between the needle shield and the plunger, rather the injection is initiated by the movement of the needle cannula assembly.

In view of the above, the independent claims are believed patentable and their allowance is solicited.

The dependent claims are believed patentable at least for depending from an allowable claim. Applicant therefore believes that the case is in condition for allowance.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any

overpayment to Deposit Account No. 25-0120 for any additional
fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

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